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February 9, 2000

**VIA FACSIMILE: (301) 827-6870**
**CONFIRMATION VIA U.S. MAIL**

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

Re: Opposition to TorPharm's Citizen's Petition for Stay of Approval of any ANDA for a generic version of Enalapril pending expiration of TorPharm's marketing exclusivity
FDA Docket No. 99P-5317/PSA 1 filed 12/8/99
Our File No. 4061-18L

Dear Sir or Madam:

This letter is submitted in opposition to the Citizen's Petition from TorPharm, dated December 7, 1999 and attached as Exhibit 1. We write on behalf of Krka Tovarna Zdravil, D.D. ("Krka"), which has filed an ANDA containing a paragraph III certification for a generic version of enalapril maleate ("enalapril"). Krka's ANDA has been tentatively approved by FDA pending expiration of U.S. Patent No. 4,374,829 covering enalapril.

TorPharm has petitioned the FDA for 180 days of marketing exclusivity for generic enalapril as *against any ANDA filer*. TorPharm's ANDA initially contained a paragraph III certification, but TorPharm amended its ANDA to contain a paragraph IV certification on March 12, 1999, eleven months before the February 22, 2000 expiration of U.S. Patent No. 4,374,829. TorPharm further contends that its marketing exclusivity should survive the expiration of this patent.

Krka opposes TorPharm's petition as contrary to statute, to regulations, and to public policy.

**A First Paragraph IV Filer Does Not Obtain**
**Marketing Exclusivity Against Paragraph III Filers**

The Hatch-Waxman Act provides marketing exclusivity for a first filer of an ANDA containing a paragraph IV certification only as against subsequent filers of ANDAs containing paragraph IV certifications. 21 U.S.C. § 355(j)(5)(B)(iv) provides:

(iv) If the application contains a [paragraph IV] certification...and is for a drug on which a previous application has been submitted under this subsection continuing [sic: containing] *such a certification*, the application shall be made effective not earlier than one hundred and eighty days after
(I) the date the [FDA] receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
whichever is earlier.
*(emphasis added)*

The relevant FDA regulation is consistent with the statute in specifying that marketing exclusivity applies only against subsequent filers of ANDAs containing paragraph IV certifications. Under 21 C.F.R. § 314.107(c)(1), the 180-day marketing exclusivity is only available to the applicant submitting the first ANDA with a paragraph IV certification and such exclusivity is effected by delaying FDA approval of subsequent ANDAs containing a paragraph IV certification on the same patent until the earlier of 180 days from 1) the date notice is received of the first commercial marketing of the drug under the first application, or 2) the date of a decision of a court holding the patent invalid or not infringed.

There is absolutely no basis in the statue or regulations for TorPharm's petition that marketing exclusivity applies against paragraph III filers.

**Marketing Exclusivity Does Not Extend Beyond Patent Expiration**

It is already FDA's position that 21 C.F.R. § 314.94(a)(12)(viii) precludes marketing exclusivity from extending beyond the term of the patent. FDA's Proposed Rules, published in the Federal Register, vol. 64, No. 151, page 42873-87 (August 6, 1999), further clarify this point. The FDA proposal states "[t]he agency is clarifying that once the patent for which the first applicant filed a paragraph IV certification expires, the first applicant is no longer eligible for exclusivity. When the first applicant is no longer eligible for exclusivity, FDA may approve all otherwise eligible ANDAs." Federal Register, vol. 64, No. 151, page 42877

TorPharm's argument that marketing exclusivity should survive patent expiration because the statute does not *require* approval of paragraph III ANDAs to be effective upon patent expiration is specious. 21 U.S.C. § 355(j)(5)(ii) states that the approval of paragraph III ANDAs "*may*" be made effective on the date of patent expiration because the ANDA may not on that date be in condition for final approval due, e.g., to an outstanding deficiency. Moreover, the FDA regulations provide that once a paragraph III ANDA is approved, the effective date of the approval is the date on which the relevant patent expires. 21 CFR. § 314.107(b)(2).

One of the major public policies underlying the Hatch-Waxman Act is to encourage drug price competition by simplifying and streamlining the approval process for generic versions of already-approved drugs and by creating incentives for generic firms to challenge patents covering approved drugs. This encourages the greatest number of generics to come on the market at the earliest possible time. TorPharm's argument that marketing exclusivity should survive patent expiration is directly contrary to Congressional intent as expressed in the Hatch-Waxman Act.

**TorPharm Cannot Satisfy the Grounds for a Stay**

As TorPharm acknowledges in its Citizen's Petition, a Petitioner may qualify for a stay only if a) the petitioner's case is not frivolous and is being pursued in good faith; b) the petitioner has demonstrated sound public policy grounds supporting the stay; and c) the delay resulting from the stay is not outweighed by public health or other public interests. Because TorPharm cannot satisfy any of these requirements, a stay is not warranted.

TorPharm's Citizen's Petition is apparently a component of its recently concocted strategy of converting its original paragraph III certification to a paragraph IV certification in the hope of gaining some advantage over its competitors. Because the "successful defense" prerequisite for obtaining market exclusivity no longer applies, TorPharm apparently believes it can obtain a competitive advantage by filing a frivolous paragraph IV certification and then arguing for marketing exclusivity. Of course, having changed its paragraph III certification to a paragraph IV certification only eleven months before expiration of Merck's U.S. Patent No. 4,374,829, TorPharm knew it had no reasonable chance of securing a judgment of invalidity or noninfringement before patent expiration. Apparently TorPharm's game is to wait until the patent expires and then move to dismiss the litigation for lack of case or controversy, while simultaneously arguing that it should receive six months of post-patent expiration marketing exclusivity because it was the first paragraph IV filer. But as discussed above, TorPharm's argument for marketing exclusivity as expressed in its Citizen's Petition is in direct conflict with the relevant statutes and regulations and contrary to Congressional intent as expressed in the Hatch-Waxman Act. To characterize TorPharm's Citizen's Petition as frivolous would be generous. It is most certainly proffered in bad faith.

Nor can TorPharm demonstrate that sound public policy grounds support a stay - - indeed public policy would dictate the opposite result. The delay resulting from a stay would prevent all ANDA filers from marketing generic enalapril until the expiration of TorPharm's 180 day marketing exclusivity – a marketing exclusivity which TorPharm is not entitled to. Such a stay is surely outweighed by the agency's obligation to follow the law and by public health and other public interests in making available a less expensive generic version of enalapril at the earliest possible time.

**Action Requested**

For all the foregoing reasons, we ask that TorPharm's Citizen's Petition be denied and specifically that FDA not stay approval of any otherwise approvable ANDA containing a paragraph III certification beyond the expiration of U.S. Patent No. 4,374,829.

Very truly yours,
COHEN, PONTANI, LIEBERMAN & PAVANE

Martin B. Pavane

Kent H Cheng

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MBP/KHC/JP/sh

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# Fax

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| **To:** | **Dockets Management Branch<br>Food and Drug Administration<br>Dept. of Health & Human Services** | **From:** | **Martin B. Pavane, Esq.<br>Kent H. Cheng, Esq.** |
| **Fax:** | **(301) 827-6870** | **Pages:** | **5 (including cover sheet)** |
| **Date:** | **Wednesday, February 09, 2000** | | |

**Re: Opposition to TorPharm's Citizen's Petition for Stay of Approval of any ANDA for a generic version of Enalapril pending expiration of TorPharm's marketing exclusivity**
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**[x] Confirmation will follow**